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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,689	11/05/2001	Yuji Hatada	215483US0	4010

22850 7590 06/26/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/985,689

Applicant(s)

HATADA ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 10, 15, 20, 21, 26, 31, and 36, drawn to alkaline proteases, classified in class 435, subclass 212.
- II. Claims 6-9, 11-14, 16-19, 22-25, 27-30, 32-35, drawn to nucleotide molecules and host cells comprising sequences for alkaline proteases, classified in class 435, subclass 252.33.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The nucleic acids of Invention II are related to the proteins of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the

natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (A). A variant of SEQ ID No: 1 wherein position 84 has been altered or a polynucleotide sequence encoding said variant.
- (B). A variant of SEQ ID No: 1 wherein position 104 has been altered or a polynucleotide sequence encoding said variant.
- (C). A variant of SEQ ID No: 1 wherein position 256 has been altered or a polynucleotide sequence encoding said variant.
- (D). A variant of SEQ ID No: 1 wherein position 369 has been altered or a polynucleotide sequence encoding said variant.
- (E). A variant of SEQ ID No: 1 wherein position 66 has been altered or a polynucleotide sequence encoding said variant.
- (F). A variant of SEQ ID No: 1 wherein position 264 has been altered or a polynucleotide sequence encoding said variant.
- (G). A variant of SEQ ID No: 1 wherein position 57 has been altered or a polynucleotide sequence encoding said variant.
- (H). A variant of SEQ ID No: 1 wherein position 101 has been altered or a polynucleotide sequence encoding said variant.
- (I). A variant of SEQ ID No: 1 wherein position 102 has been altered or a polynucleotide sequence encoding said variant.

- (J) A variant of SEQ ID No: 1 wherein position 103 has been altered or a polynucleotide sequence encoding said variant.
- (K) A variant of SEQ ID No: 1 wherein position 104 has been altered or a polynucleotide sequence encoding said variant.
- (L) A variant of SEQ ID No: 1 wherein position 105 has been altered or a polynucleotide sequence encoding said variant.
- (M) A variant of SEQ ID No: 1 wherein position 106 has been altered or a polynucleotide sequence encoding said variant.
- (N) A variant of SEQ ID No: 1 wherein position 136 has been altered or a polynucleotide sequence encoding said variant.
- (O) A variant of SEQ ID No: 1 wherein position 193 has been altered or a polynucleotide sequence encoding said variant.
- (P) A variant of SEQ ID No: 1 wherein position 342 has been altered or a polynucleotide sequence encoding said variant.
- (Q) A variant of SEQ ID No: 1 wherein position 46 has been altered or a polynucleotide sequence encoding said variant.
- (R) A variant of SEQ ID No: 1 wherein position 205 has been altered or a polynucleotide sequence encoding said variant.
- (S) A variant of SEQ ID No: 1 wherein position 54 has been altered or a polynucleotide sequence encoding said variant.
- (T). A variant of SEQ ID No: 1 wherein position 119 has been altered or a polynucleotide sequence encoding said variant.

(U) A variant of SEQ ID No: 1 wherein position 138 has been altered or a polynucleotide sequence encoding said variant.

(V) A variant of SEQ ID No: 1 wherein position 148 has been altered or a polynucleotide sequence encoding said variant.

(X) A variant of SEQ ID No: 1 wherein position 195 has been altered or a polynucleotide sequence encoding said variant.

(Y) A variant of SEQ ID No: 1 wherein position 247 has been altered or a polynucleotide sequence encoding said variant.

(Z) A variant of SEQ ID No: 1 wherein position 124 has been altered or a polynucleotide sequence encoding said variant.

(AA) A variant of SEQ ID No: 1 wherein position 107 has been altered or a polynucleotide sequence encoding said variant.

(BB). A variant of SEQ ID No: 1 wherein position 257 has been altered or a polynucleotide sequence encoding said variant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-6 EST.

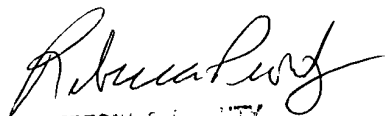
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.


REBECCA E. PLAUTY
PRIMARY EXAMINER
GROUP 1A00
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